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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,193	01/13/2005	Pnina Fishman	FISHMAN13A	8661

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EXAMINER	
CRANE, LAWRENCE E	

ART UNIT	PAPER NUMBER
1623	

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05/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,193	FISHMAN ET AL.	
	Examiner	Art Unit	
	L. E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *January 13, 2005 (Prelim. amdt)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 January 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/13/05 and 8/1/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The Abstract of the Disclosure is objected to because is does not meet the requirement of the MPEP for US application. Correction is required. See MPEP 608.01(b).

Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts, compounds or compositions, the general nature of the compound or composition should be given as well as its use, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary. Complete revision of the content of the abstract is required on a separate sheet.

The Abstract is grammatically incorrect because the first "sentence" is not a complete sentence. Editing for readability and correction of grammatical errors is respectfully requested.

This application has been filed with informal drawings acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Examiner suggests that the Figure needs to be edited for clarity of printing in black and white.

The instant disclosure fails to include "Cross-References to Related Applications." See 37 C.F.R. §1.78 and MPEP at §201.11. Applicant is respectfully requested to include the requested information as the first paragraph of the disclosure.

Claims **1-10** have been cancelled, no claims have been amended, the disclosure has **not** been amended, and new claims **11-15** have been added as per the preliminary amendments filed January 13, 2005. An Information Disclosure Statement (IDS) filed April 13, 2005 and August 1, 2005 have been received with all cited references and made of record.

Claims **11-15** remain in the case.

Note to applicant: when a rejection refers to a claim **X** at line y, the line number "y" is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

Claims **11-15** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are directed to the treatment of "multiple schlerosis" but the instant disclosure has failed to produce any teaching or experimental data wherein this particular disease condition, either *in vitro* or *in vivo*, has been shown to be effectively treated by any compounds specifically or generically disclosed herein. Therefore the written description of the instant disclosure is deemed to be inadequately supportive of the instant claimed subject matter.

Claims **11-15** are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabled for the treatment of "autoimmune encephalomylitis (EAE) at pages 12-13 and in Figure 1, does not reasonably provide enablement for the treatment of any other disease condition including "multiple sclerosis." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of "undue experimentation" is appropriate are as follows:

A. The breadth of the claims: The claims are directed to the treatment of multiple sclerosis by any compound classified as an adenosine A_3 agonist, abbreviated as "A3RAg."

B. The nature of the invention: The invention is directed to the treatment of multiple sclerosis by administration of an adenosine A_3 agonist, particularly one of the agonists listed in claim **15**.

C. The state of the prior art: The instant prior art of record include one report wherein multiple sclerosis has been effective treated by the administration of 2-chloro-2'-deoxyadenosine. Other reports are not definitive concerning whether a class of compounds can effectively treat any specific disease condition, but typically rely on the effect of the compounds on a model system wherein the binding to an adenosine A_3 agonist or antagonist can be measured. Confusion arises concerning whether the binding of an agonist or an antagonist (e.g. the Linden patents) is more likely to be effective, and there is no test data to provide a basis for reaching a conclusion as to which class of compounds is more likely to be effective in the treatment of multiple sclerosis or any other disease condition wherein the outcome is presently thought to be possibly influenced by the administration of an adenosine A_3 agonist or antagonist.

D. The level of one of ordinary skill: The ordinary practitioner in administration of a medicinal substance is medically trained.

E. The level of predictability in the art: The variety of incomplete reports of substances though to be possibly effective in the treatment of multiple sclerosis, and the single report of an effective treatment, make predictability very low because of the lack of an agreed upon theory of how to effectively treat this disease. The instant disclosure's single example does not effectively address this problem.

F. The amount of direction provided by the applicant: The instant disclosure only provides a single example and the disease treated in not multiple sclerosis.

G. The existence of working examples: The instant disclosure only reports one set of data points in Figure 1 and thereof is deemed to have only a single working example wherein the disease EAE is shown to be effectively treated by the administration of a compound selected from the instant disclosed compounds.

H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure is deemed to be excessive because the instant claims are directed very broadly to all adenosine A_3 agonists as effective the in the treatment of multiple sclerosis. In addition, there is some question in the prior art concerning what class or classes of adenosine A_3-binding substances are likely to be effective. And finally, the instant disclosure does not

provide any data wherein multiple sclerosis has been shown to be effectively treated by any compound specifically or generically disclosed herein.

Claims **13 and 14** are objected to because of the following informalities:

In the noted claims applicant has mixed formats for alternative listing of substituent groups. The two formats are either Markush format ("selected from the groups consisting of A, B ... **and** Z") or the presence of the term -- **or** -- between the last two members of the group. Applicant is respectfully requested to selected one format and avoid combining formats in the interest of clarity. Examiner notes that claim **15** has a proper Markush format illustrated.

Appropriate correction is required.

Claims **11-13** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims **11 and 12** the term "adenosine A_3 receptor agonist" is generic and not defined by any particular chemical structure or structures, thereby rendering the metes and bounds of the instant claim indefinite.

In claim **13** at line 38, the term " wherein when R_4 is hydrogen then " appears to be a proviso. Applicant is respectfully requested to introduce the term "proviso" to make clear that the scope of the claim is being limited by the subsequent paragraph. See also line 49 wherein a proviso is also apparently present. Examiner also respectfully requests that the provisos be moved to the end of the claim so that the definition of "Z" is not seen to be included with the proviso unless applicant specifically so intends.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

(e) the invention was described in

(1) an application for patent described under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application filed under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)."

(f) he did not himself invent the subject matter sought to be patented."

Claims **11-12** are rejected under 35 U.S.C. §102(**b**) as being anticipated by **Chan et al. '170** (PTO-1449 ref. **AE**).

Applicant is referred to column 3, lines 1-23, wherein compounds identified as adenosine A_3 receptor agonists are taught to be effect in the treatment of inflammatory diseases wherein leukocytes are involved, a class of diseases that includes multiple sclerosis.

Claims **11-12** are rejected under 35 U.S.C. §102(**b**) as being anticipated by **Castelhano et al.** (PTO-1449 ref. **AA**).

Applicant is referred to page 8, and further to claims ***39 and 42*** wherein the instant claims are anticipated.

Claims **11-12** are rejected under 35 U.S.C. §102(**a**) or (**b**) as being anticipated by **Dolezal et al. '791** (PTO-892 ref. **L**).

Applicant is referred to page 69, structural formula "I" and to page 97, claim ***9*** wherein the instant claims are anticipated.

Claims **13-15** would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. §112 set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < http://pair-direct.uspto.gov >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

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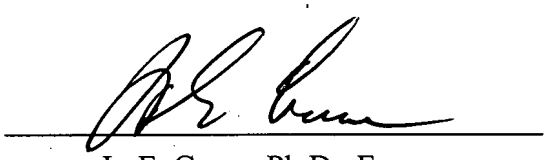

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